

**Notice of Allowability**

Application No.

10/530,584

Applicant(s)

MOLINA ET AL.

Examiner

Art Unit

Anand U. Desai, Ph.D.

1656

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to April 7, 2005.
2. ☒ The allowed claim(s) is/are 1-14.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is October 10, 2002.

### EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Stephanie D. Adams on November 13, 2006.

Examiner's Amendment to the claims:

1. (Currently Amended) An isolated nucleic acid selected from the group consisting of:
  - (a) a nucleic acid according to SEQ ID NO: 2 encoding preduramycin;
  - (b) a nucleic acid according to SEQ ID NO: 4 encoding produramycin;
  - (c) nucleic acids that are at least 95 percent identical in sequence to nucleic acids of (a) or (b) above and which encode said preduramycin or produramycin;
  - (d) nucleic acids that differ from the nucleic acids of (a), (b), or (c) above due to the degeneracy of the genetic code, and which encode a preduramycin or produramycin encoded by a nucleic acid of (a), (b), or (c) above, and  
wherein the preduramycin and produramycin are precursors of duramycin, which is an antibiotic.

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8. (Currently Amended) An isolated recombinant host cell comprising a heterologous nucleic acid according to claim 1 and capable of expressing the encoded preduramycin or produramycin.

9. (Currently Amended) The recombinant host cell of claim 8, wherein said host cell is gram positive bacteria.

10. (Currently Amended) The recombinant host cell of claim 8, wherein said cell is selected from the group consisting of genus *Bacillus*, genus *Streptomyces*, and genus *Streptococcus*.

11. (Currently Amended) A method of making preduramycin, produramycin, or duramycin, comprising:

culturing a suitable host cell according to claim 8 under conditions which the encoded preduramycin or produramycin is expressed; and then

collecting preduramycin, produramycin or duramycin from said cultured host cells.

***Allowable Subject Matter***

3. Claims 1-14 are allowable.

4. The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose an isolated nucleic acid selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 4, and nucleic acids that are at least 95 identical in sequence to SEQ ID NO: 2, SEQ ID NO: 4, which encode said preduramycin or produramycin. Qi et al. (U.S. Patent 6,342,385 B1) disclose the nucleic acid sequence for lantibiotic, mutacin I, and the transformation of a host cell with the nucleic acid sequence (see claims). Bibb et al. (US

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2004/0101963 A1) disclose the nucleic acid sequence for another lantibiotic, cinnamycin, and the transformation of a host cell with the nucleic acid sequence (see Abstract, and claims).


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

November 13, 2006



ROBERT A. WAX  
PRIMARY EXAMINER